# PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council held Tuesday, November 15, 2005, 10:00 a.m., at the Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Chair Paul J. Cote, Jr., Ms. Phyllis Cudmore, Mr. Manthala George, Jr. (arrived late at 10:05 a.m.), Mr. Albert Sherman, Ms. Janet Slemenda, Mr. Gaylord Thayer, Jr. and Dr. Martin Williams. Ms. Maureen Pompeo and Dr. Thomas Sterne were absent. Also in attendance was Attorney Donna Levin, General Counsel.

Chair Cote announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance. In addition, Chair Cote noted that the December Public Health Council meeting has been rescheduled from December 13, 2005 to December 20, 2005.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Mr. Pelman Talebian, Acting Division Director and Dr. Susan Lett, Medical Director, Division of Epidemiology and Immunization; Ms. Suzanne Condon, Director, Center for Emergency Preparedness, and Associate Commissioner, Center for Environmental Health; Dr. Paul Dreyer, Associate Commissioner, Center for Quality Assurance and Control; and Attorneys Kalina Vendetti, Melissa Lopes, and Carol Balulescu, Deputy General Counsels, Office of the General Counsel.

## STAFF PRESENTATION: "UPDATE ON INFLUENZA PANDEMIC PLANNING", BY SUZANNE K. CONDON, DIRECTOR, CENTER FOR EMERGENCY PREPAREDNESS, ASSOCIATE COMMISSIONER, CENTER FOR ENVIRONMENTAL HEALTH; AND DR. SUSAN LETT, MEDICAL DIRECTOR, DIVISION OF EPIDEMIOLOGY AND IMMUNIZATION:

Mr. Pelman Talebian, Acting Division Director, Division of Epidemiology and Immunization, Department of Public Health made a slide presentation. He said in part, "I am going to be giving a brief update on the current flu supply situation before we go into discussion on pandemic planning…We are fairly unique in that, we, the state health department, purchases approximately 50% of all the vaccine that is used in Massachusetts. Most of the vaccine is prioritized for high risk individuals, senior long term care facilities, community health centers, pediatric practices and pretty much most of the vaccine that is used in public health clinics throughout the state. We have some federal funding that helps to pay for some of the vaccine that then goes to pediatric primary care providers as part of our entitlement program. The rest of the vaccine supply is purchased privately by individual health care providers and reimbursed by insurance companies, depending on the plan's coverage."

"As of today", continued Mr. Talebian, "Nationally about 71.5 million doses have been distributed to date compared to 52 million last year. Last year was a severe shortage year. Of the 71.5 million doses distributed this year, 55 million are by Sanofi Pasteur, which is pretty much the largest manufacturer currently; 7.5 million by GlaxoSmith/Kline, who is a new company into the market

for flu vaccine; at least 8 million by Chiron; and 1 million by MedImmune. MedImmune produces the FluMist, the live attenuated vaccine. The projections are 81 million doses for distribution this year compared to 57 million last year. The highest dose ever distributed in a single season was 83 million and the Centers for Disease Control (CDC) is predicting that we may go above that amount this year. Supply is looking very good. In Massachusetts, 1.4 million doses, both public and private, have been distributed to date and that compares to 1 million doses last year. We anticipate at least about 1 ½ million doses being distributed this year, compared to 1.3 million for all of last season. Seven hundred twenty-eight thousand forty doses were purchased by us this year, and those have all been received and distributed…There is also the likelihood of some late season doses coming in December…"

Susan Lett, M.D., Medical Director, Division of Epidemiology and Immunization, gave an update on the status of avian influenza in the international scene, the plans of the United Nations (UN) and World Health Organization (WHO) and the CDC recommendations. She said in part, "Late September and October, there was an explosion of attention around the avian influenza situation internationally. It has been appearing in a number of papers…and we are now at Pandemic Alert Stage 3. There are six (6) phases according to WHO. One is when there is low risk for human cases, Two is when a new virus arises in animals, but there is no human cases, and the pandemic alert is when there are very limited human-to-human transmission, and that is the phase we are in right now (phase three)…In the United States there are 36,000 deaths every year and more than 200,000 hospitalizations, and between 15 million and 50 million people infected every year from the flu."

Dr. Lett said, "There's three necessary prerequisites for a pandemic. There has to be emergence of a new strain that can infect humans after originating in animals. There has to be person to person transmission and it has to replicate in humans and cause severe illness and then there has to be efficient human to human transmission that leads to multiple generation. A new strain that emerged, beginning in 1997 is H5N1 and over time, H5N1, which arose in poultry, has begun to affect humans."

<u>Earlier pandemics noted</u>:

1889 (H3 or H2)

1918 (Spanish Flu H1N1) which originated in birds and transmitted directly into humans killed many adolescents and young adults which was unusual since flu usually affects the very young or very old. In Massachusetts: 40 million people died; 500,000 in the USA; and up to a hundred million worldwide.

1967-1968 (Asian Flu H2) 66,000 deaths in the USA; one to two million people died worldwide.

1968 (Hong Kong Flu) 28,000 deaths in USA and 700,000 people died worldwide.

Dr. Lett stated, "…Migratory water fowl are this huge reservoir for Influenza A and they can transmit it to many other mammals…What is happening in Asia that is making things sort of evolve probably more fast is that the number of domestic chickens in Asia has increased algorithmically as

people's standard of living has improved, and the flyaways for the birds have been lost and these migratory fowl are sort of really interacting very closely with the poultry in Asia…Avian influenza happens all the time. It is called low pathogenic if it is not causing tremendous die-off in animals. New strains have emerged over the last 15 years, H7, H5, and H9 resulting in very little human illness with the exception of H7 in the Netherlands in 2003 where one veterinarian died. With the exception of H5 the avian strains we are watching are not causing a lot of human illness but anyone of these avian strains could be the one that could cause the next pandemic, not necessarily H5. Since 2003, the avian outbreak has affected sixteen countries in Asia and Europe, and since May has spread very quickly through Russia, Pakistan and Turkey, to Romania and Croatia. It affects migratory birds and domestic poultry, and over two hundred million birds are dead, either due to illness or slaughter, and it is an unprecedented outbreak in terms of what is called high pathogenicity avian influenza. High pathogenicity is a strain that results in a lot of deaths. The strain started out in Eastern Asia and is now into Eastern Europe…Current outbreaks are in countries in Eastern Europe, Romania, Turkey and Croatia."

Dr. Lett continued, "What are the concerns? It has become pandemic in wild birds, its magnitude is unprecedented, it is spreading rapidly through the flyaways. Domestic ducks have become asymptomatic carriers and are shedding the virus for much longer. Domestic ducks are in contact with other domestic poultry, like chickens. It is expanding its humalian host range; pigs, domestic cats and wild cats have been identified as being infected, and the virus is pretty hardy and remaining in the environment for many days longer than regular influenza. In addition, there has been an ongoing evolution of the virus that has been pretty rapid since 2003, and two different strains have diverged, and the virologists that study this are worried about the rate of mutation that is going on. If several more mutations go on, they feel it really could adapt itself to humans, as well as become more resistant to antiviral agents. Other things that are happening, in terms of the epidemiology, is the age range of humans has spread out and is now including more young adults. It was primarily children in 2003 and 2004. The mortality rate in humans is lower, and is extremely serious because it had been 80 to 90%, and is now 50%, and to contrast that, in 1918, it was about 1 to 2%. More of the population was affected, but the mortality rate was only 1 to 2%. If a virus is killing its host, it is not a good vector for epidemics or pandemics, but as the mortality rate decreases, that could increase people's ability to transmit to others. There have now been two situations where there have been documented human-to-human transmissions, mostly involving health care workers, but almost all human cases have been associated with exposure to poultry, so far."

Dr. Lett said further, "The other thing that is worrisome is family clusters and community outbreaks in North Vietnam, where we can't rule out person-to-person transmission, and we can't rule out where the exposures are occurring. There is widespread resistance to the antivirals (amantadine and rimantadine). To date most of the avian strains are still sensitive to oseltamivir, or Tamiflu, but increasing resistance has been reported in birds. There has been at least one case of resistance documented in humans, and we don't have a lot of data on zanamivir or Relenza, which is the other antiviral agent. What is worrying people now is two of the three necessary prerequisites have been met with H5N1."

Dr. Lett noted the following: that avian influenza has a very rapid onset; chickens can be fine in the morning and by the end of the day be dead. It is a multi-organ virus, involving the pancreas and the heart. It addition to being respiratory illness and multi-organ illness, it is a gastrointestinal illness

and the virus is shed in the stool which make it difficult to control. In Asia people live close with their poultry. In humans, it has got a slightly longer incubation period, a much longer potential infectious period. It starts out like typical influenza, then progresses with fever, myalgia, cough, sore throat into diffused primary viral pneumonia, severe respiratory disease or respiratory distress syndrome, multi-organ failure, encephalitis, cardiac abnormalities, and it is resistant to adamantines. The current recommendations for treatment or control are cough etiquette, isolation, precaution and personal protective gear, antiviral treatment, staff should be vaccinated, and you should limit the staff that is caring for patients.

On the international level, Dr. Lett indicated what is being done:

- WHO has an Avian Influenza web site with a lot of information on it: reports and surveillance data from it own organization as well as from the Food and Agriculture Organization and the World Organization for Animal Health. WHO has developed a strategic action plan this past September, as part of an international plan to control spread, reduce opportunity for human infection, strengthen the early warning system, contain or delay spread at the source, reduce morbidity, mortality and social disruption, and conduct research to guide response measures.

- In Asia, insecticide is being sprayed and cohorting of animals (i.e., animals are being watched; not introducing new herds into the old herds until they are observed for shedding and other problems).

- There is an International Partnership on pandemic influenza, led by the United States along with WHO.

- In the USA, the CDC has issued an outbreak notice on its travel web site with suggestions of avoiding contact with poultry, washing eggs, monitoring your health and before you report to a health care setting for evaluation, to tell them where you are so the appropriate precautions can be taken and any possible introduction contained. In addition, flight crews have received instructions on how to screen passengers.

- In Massachusetts, about every month or so, people arrive here with the case definition for surveillance, and the state laboratory does testing for PCR (polymerase chain reaction). The state is contacted by health care providers.

  Dr. Lett clarified the above, "People are concerned so we do testing to help rule out any possibilities of even regular influenza. Health care providers take this seriously. They consult with us frequently, and this all fits into this whole international plan for early protection and containment. This is going on across the world, in our country, and in our state."

Commissioner Cote, Chair added, "…In the federal plan, one of the things they call for is increased and enhanced surveillance efforts, which really are those efforts to both identify potential cases and actually screen to make sure, to assess whether or not they are a risk. I think what Dr. Lett is

referring to is an example of where, in Massachusetts, we have had this active and stepped-up surveillance activity for some time now."

Ms. Suzanne Condon, Director, Center for Emergency Preparedness, and Associate Commissioner, Center for Environmental Health, reported what Massachusetts has been doing to prepare for pandemic influenza in Massachusetts. She said, "…A lot of people have been talking about this recently, but the reality is, in Massachusetts, we have been preparing or trying to put together plans to prepare since the mid-1990s and that started with our Bureau of Communicable Disease Control staff and specifically, the Epidemiology and Immunization staff." Ms. Condon noted the Department's history of pandemic planning:

1994: DPH staff attends the first CDC Conference on Pandemic Planning. Throughout the 1990s staff developed a draft plan.

1999: DPH established a local Pandemic Planning Committee that was composed largely of state and local public health officials.

2000: DPH had the first version of the Pandemic Preparedness Plan exercised with the Mass. Emergency Management Team and that first version was revised and posted for public review and comment.

2001: DPH developed a template for local infectious disease monitoring and response.

2002: The Emergency Planning and Response sections were drafted. The local Pandemic Planning template was also developed and distributed. Also in 2002, DPH established the first Statewide Emergency Preparedness Advisory Committee.

2003: DPH established the new Center for Emergency Preparedness with an aim towards coordinating and centralizing all preparedness and response activities. All 351 cities and towns of Massachusetts agreed to collaborate and regionalize into 15 regional coalitions.

2004: DPH developed the Local Risk Communication Planning template and the Influenza Planning Guide for State and Local Officials. The Department also officially established a Department of Public Health Executive Committee.

2005: DPH distributed an Emergency Dispensing Site Management and Operations Plan to local health officials which calls for almost 500 dispensing sites to be made available across the state in the event that the state needs to administer prophylaxes. The DPH team developed a flu pandemic flyer that has been published and disseminated extensively across the state. The influenza pandemic document has been updated and will continue to be updated every six to eight weeks.

Ms. Condon continued, "As Dr. Lett mentioned, there are fact sheets on avian flu that have been prepared and issued. We did another talk back in January with the Executive Office of Public Safety and a group called the New England Disaster Information Exchange Group. We have provided regular updates for the Governor and have done legislative briefings on pandemic planning. We established, across the Health and Human Services Secretariat, a Senior Executive Team for

continuity of operations planning to all of state government. We have two forums coming up, one is today, a simulated exercise with our New England Disaster Information Exchange Group. They are the continuity of operations planners for private businesses, largely in New England. The elements of our state and local pandemic planning have really focused on four major areas: public education and outreach efforts and campaigns, assuring the capacity of the health care system itself, assuring the involvement of our public safety partners. For the communication strategy, as Dr. Lett mentioned, many people want to know how severe the pandemic will be, what circumstances might the Department and the Commonwealth decide to close schools, restrict travel, impose quarantine, and what can I do as a member of the public? In terms of the severity of the pandemic, we keep an eye on things, but there is no real way of knowing for certain when the pandemic will occur, or how severe it might be. We have examples of vast extremes, based on 1918, and then we have some of the pandemics that have had lesser impacts such as 1968. At this point, we are planning for a pandemic somewhere in between, one that might affect one in six people, or approximately 17% of the population. What about a vaccine? Vaccine can only be developed after the flu strain has been identified and, therefore, we are sort of operating under the assumption that there will be no vaccine available to us for the first several months of trying to respond to a pandemic. Once the CDC and the vaccine manufacturers are able to develop a flu vaccine, our best estimate that we have received is that we would get about 450,000 doses from that initial provision and, again, it won't be available for at least six months once the pandemic hits."

Associate Commissioner Condon said further, "Antivirals are not necessarily the magic solution that some people have thought and one of the things that made me the most concerned from a preparedness perspective has to do with inappropriate use. If people, the public, were to begin to stockpile, then it could lead to development of resistant strains. As Dr. Lett mentioned, we have already seen some of that happen with these other antivirals. What can the public do? I am not going to read all of these because they are available on the facts sheets. Public Health people are big on washing hands. It prevents a lot of public health problems and so as basic as that sounds, we continue to push that message out. I have seen more hand cleaners around and I won't mention product names, but people are using them a lot. The message is getting out there. What the public can do best is, if they get sick, they need to stay home from school or work. The extent to which we can try to contain things once a pandemic occurs, once people are sick with the flu, any flu, then it makes sense to stay away from people that you can expose. In terms of our preparedness programs, we have enhanced surveillance systems to ensure early detection of influenza. We have, in the Boston area, specifically with the City of Boston and all the Boston hospitals, volume-based surveillance through the Boston hospital emergency departments. We work closely with them, and we actually fund the city to do this work."

Council Member Sherman asked if the surveillance system works. Dr. Lett and Ms. Condon assured him that it does. For instance, Dr. Lett noted, if a Boston hospital suspects cases, the hospital contacts the city of Boston which in turn contacts the Department of Public Health, specifically the Immunization Program. The Immunization Program screens the cases and then sends over kits by courier for the collection of digestive specimens. The State Laboratory in on alert to come in any time that it is needed for testing 24 hours a day, 7 days a week. False alarms have occurred so the Department knows the system is working.

Ms. Condon added further, "The Department through its Registry of Vital Records and Statistics receives death certificates. This information could be useful in pandemic planning so the Department is working with local officials to expedite the time frame of the reporting. We have the Health and Homeland Alert Network, a statewide communications system that links hospitals, local public health and public safety. Within moments, we can reach hundreds, if not thousands of people through that system. We have also developed an enhanced communication system through the provision of Nextel phones and now, this year, we will be providing satellite phones to the hospitals. That system is tested frequently and it works."

Ms. Condon continued, "Our hospital preparedness planning has been divided across six regions and according to the Health Resources and Services Administration, their benchmark requires surgery capacity to handle 500 acutely ill patients per million population and that is about three million people in Massachusetts. Our plans are going way beyond that. We have also worked with the hospitals on personnel protective equipment. Availability of hospital and EMS services in terms of surgical capacity: we have been working with the hospitals such that, through the cancellation of elective procedures and other activities; we could have, within 12 to 24 hours, forty five hundred and forty-five surgical beds available. There is also an additional thirty-five hundred and fifty-eight unstaffed beds that are licensed, that could be made available if additional personnel were identified, and we have some volunteer registration systems in place."

On continuity of operations, Ms. Condon stated, "Both in government and non-government, the critical infrastructures need to be maintained; public safety, transportation, financial institutions, utilities, food, water and supplies, and coordination with some of these larger organizations that I mentioned earlier, NEDRIC, the private sector group of business continuity planners. We want to ensure for EOHHS operations, we focus on the continuing patient care and client care, and support services, and ensuring that we have administrative management and oversight to assure that those important activities continue. Our continuity of operations has been focused on direction and control, agency specific continuity of operations plans and the community providers…Seventy percent of the work EOHHS does is conducted by community providers across the state. We have just finished a series of provider meetings, going over what is necessary to put in place a Continuity of Operations Plan. We have asked that these plans be completed at the provider level by December 2nd. There will be a certification plan on a web page, that they have to submit, stating that they have indeed done this, and we are establishing regional teams of Health and Human Services staff to work with providers at the regional level and to integrate those plans."

In closing, Associate Commissioner Condon said, "Lastly, the Executive Office of Public Safety was required by the Department of Homeland Security to prioritize various emergency scenarios that are part of our HPPD-8 Directive. There are about 15 different scenarios. Each state was required to select three. Of those, Public Safety did select Pandemic Influenza and so they have been working very closely with us and with all state government agencies on Continuity of Operations Plan. Anyway, that is where we are today and we are working on new things each and every day." A brief discussion followed, Chair Cote noted that history has told us that once there is effective human-to-human transmission that a pandemic circles the globe within approximately two months time.

**NoVote/Information Only**

**MISCELLANEOUS: REQUEST FOR ADOPTION OF THE MAGISTRATE'S TENTATIVE DECISION AS THE DEPARTMENT'S FINAL DECISION IN THE MATTER OF THE DEPARTMENT OF PUBLIC HEALTH V. MAPLE HILL REST HOME, INC., SPRINGFIELD MA:**

Attorney Kalina Vendetti, Deputy General Counsel, Office of the General Counsel, presented the Maple Hill Rest Home matter to the Council. She informed the Council, "On September 7, Magistrate Judith Anne Burke issued a tentative decision, upholding the Department's agency actions against the Maple Hill Rest Home. Maple Hill is a 32-bed rest home located in Springfield, MA. At the time of the hearing, the Department had issued fines totaling seventy-five hundred dollars and had imposed a limitation on admissions against the rest home. We based these actions on almost a year of investigations and follow-ups that show that the Maple Hill Rest Home is chronically unwilling or unable to abide by the Department's regulations that were promulgated to protect residents in this setting. For example, the Department found that the Maple Hill didn't provide the nursing services required to give patients vital medications in appropriate doses and at appropriate times, and they also didn't supervise residents to help keep them safe from hurting themselves with sharp objects or illegal drugs. After a hearing on the merits, which was held on July 11, this summer, and in a strongly worded decision, Magistrate Burke upheld all the Department's actions against Maple Hill. What the Division is requesting is that the Commissioner and the Public Health Council adopt Magistrate Burke's tentative decision as the final decision for the Department of Public Health."

A discussion followed by the Council. Council Members asked about the status of the rest home now and its management problems. As a result of the Council's concerns, Atty. Vendetti noted the following:

- DPH has initiated an action to revoke the license for the rest home but in the interim, the rest home has come into full compliance (corrected all the deficiencies) therefore the Department is negotiating with the rest home on a settlement agreement rather than revoking the license.

- The licensees operate another nursing home, the Lord Nathan Rest Home, however, that facility is in full compliance with the Department's regulations.

- Maple Hill deals with a difficult patient population.

- The Admission Freeze on admitting new patients to Maple Hill will be lifted, if not done already, as soon as the Supervisor from the Division of Health Care Quality determines that the facility is in fact in full compliance.

Dr. Paul Dreyer, Associate Commissioner, Center for Quality Assurance and Control, added, "This facility will receive frequent unannounced inspections until we are confident that the compliance that they have achieved on our follow-up inspections is sustained. We have probably been to the rest

home five or six times in the past year, and it wouldn't surprise me if we were in that many times in the coming year, to assure that the facility maintains compliance. So, it is not the case that once we find them in compliance, that they will switch back to an every two-year licensure visit."

A directive from Council Member George requires a follow-up report on how the rest home is functioning be provided to the Council in about six months time.

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve and affirm the **Adoption of the Magistrate's Tentative Decision as the Department's Final Decision in the Matter of the Department of Public Health v. Maple Hill Rest Home, Inc.**

**PROPOSED REGULATIONS:**

**INFORMATIONAL BRIEFING ON PROPOSED REGULATIONS 105 CMR 960.000: BIOTECHNOLOGY:**

Attorney Melissa Lopes, Deputy General Counsel, Department of Public Health, presented regulations 105 CMR 960.000, on Biotechnology to the Council. She said, "…These proposed regulations seek to interpret and implement Mass. General Laws, Chapter 111L, Biotechnology. As you may be aware, Chapter 27 of the Acts of 2005, an act enhancing regenerative medicine in the Commonwealth, was enacted on May 31st of this year. Section I of the act added a new chapter to the General Laws, Chapter 111L, entitled Biotechnology. You should have received a copy of Chapter 111L in your materials. Chapter 111L addresses several matters related to the biotechnology industry in Massachusetts including registration of institutions conducting human embryonic stem cell research, permitted and prohibited research methods, informed consent protections for individuals undergoing infertility treatment and for individuals donating genetic materials and pre-implantation embryos for research, protection for employees of research institutions performing human embryonic stem cell research, the establishment of a public institutional review board at the University of Massachusetts Medical Center, the establishment of a public bank for the purpose of collecting and storing umbilical cord blood and placental tissue, and the establishment of a biomedical research advisory council. DPH has authority to promulgate the proposed regulations as provided by the Act. Section 10 of Chapter 111L gives the Department of Public Health responsibility for enforcing Chapter 111L and confers the authority to adopt regulations related to the administration and enforcement of the Chapter. These draft regulations, 105 CMR 960.000, set out what is and what is not permissible with respect to research concerning the creation of embryos and donations, transfers of gametes, cadaveric tissue and embryos."

Attorney Lopes continued, "In particular, these regulations seek to clarify that the prohibition against any person knowingly creating embryos by the method of fertilization for donation, under Chapter 111L, Section 8b, also means that no person may knowingly create embryos by the method of fertilization for use. In essence, researchers may not create fertilized embryos solely for donation to, or use in research. These prohibitions are addressed in 960.005A and B of the proposed regulations. In addition, Section 960.006C pulls together and lists all the requirements with respect to the donation of genetic materials or pre-implementation embryos found in various sections of Chapter 111L. The remaining provisions of the proposed regulations merely track the statutory provisions on donations and permissible and non-permissible research. These proposed regulations did not address

all the provisions of Chapter 111L. It is anticipated that, as other provisions require clarification or more detail, additional regulatory provisions will be promulgated."

Attorney Lopes said further, "The Department will release the proposed regulations for public hearing and comment and return to the Council with a final recommendation. Please note that Section 10 of MGL, Ch.111L also sets out procedures for the promulgation of regulations. These statutory procedures were mandated in addition to the Massachusetts Administrative Procedure Act; Chapter 111L must be published 90 days prior to a public hearing rather than the conventional 21 days under Ch. 30A. In addition, notice must be published in several newspapers, a medical journal published in Massachusetts, and a biotechnology newspaper or trade journal. Notice must also be sent to the Committee on State Administration and Regulatory Oversight of the General Court, which may, in consultation with the Joint Committee on Economic Development and Emerging Technologies, review the regulations and hold public hearings of its own. The proposed regulations will also be reviewed by the Biomedical Research Advisory Council, established by the Act. Consequently, there may be a significant lapse of time before the Department returns to Council with the final set of recommendations."

Council Member Sherman noted a correction in the staff report to the Council. The staff report states the establishment of a public Institutional Review Board at the University of Massachusetts Medical **Center.** It should be corrected to University of Massachusetts Medical **School**. Center should be changed to School. Council Member Thayer asked why the application process wasn't in the draft regulations. The Department's General Counsel Donna Levin responded and said in part:

"These regulations do not address every provision in the Act. The regulations are basically for the purposes that we have laid out here. There is a lot that is required by the Act that can be implemented administratively, and needed to be implemented fast. For example, the registrations all have to be done and people in compliance by November 27th. There is no way, under procedures required under this Act with the additional administrative procedures to promulgate regulations, that could have been set out in regulations and gotten in place for people to know what they had to do. We have made the outreach. Everyone who needs to register has been outreached to, and we have an application and a process, and they have been registering with us for that November 27th deadline. There is a lot of leeway for the administrative agencies, such as this, to implement what it has to do under a statute without a regulation spelling everything out. As we go along and know more of where the questions are, the issues are, applications needed, we will continually be coming to the Council to promulgate regulations in that area. There is no way we could have done that, and complied with the Act…"

**No Vote/Information Only**

**INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 140.000: LICENSURE OF CLINICS:**

Attorney Carol Balulescu, Deputy General Counsel, Department of Public Health, provided an informational briefing to the Council on amendments to 105 CMR 140.000. Atty. Balulescu noted, "The Department has been working for several years with an advisory group to update the sections in the regulation that set forth requirements for mental health clinics, which were last updated in

1994, in order to reflect current standards of practice. In addition to making technical corrections and correcting typographical errors, these amendments will recognize current standards of practice and update requirements for mental health clinics. These amendments will require the same standard of care for home visit clients as at the clinic sites, update definitions for professional staff, clarify supervisory requirements, provide clarification for requirement mental health services and remove redundancies, review requirements for treatment plans, differentiate between the responsibilities of a multi-disciplinary treatment team and other professional staff, recognize the prescribing authority of other practitioners and responsibility of clinic psychiatrists for supervision of prescribing practices, expand the list of professionals that qualify as members, change the requirements for the composition of the multi-disciplinary team, and update requirements for mental health outreach programs. The Department intends to hold a public comment hearing on December 14th to receive comments on these proposed amendments. Following the hearing, Department staff will return to the PHC to provide a review of the testimony, to present any changes proposed in response to the testimony and to request approval to promulgate the proposed amendments. If you have any questions, I will be happy to answer them."

**Information Only/ No Vote**

**REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 150.000 LICENSING OF LONG TERM CARE FACILITIES ("The Rolland Amendments"):**

Attorney Kalina Vendetti, Deputy General Counsel, Department of Public Health, presented "the Rolland Amendments" to the Council. It was noted, "Loretta Rolland, et al v. Cellucci is a class action law suit filed in 1998 by mentally retarded residents of long-term facilities. The Amended Complaint alleged that the Defendants failed to provide plaintiff class members with specialized services and community residential supports in a timely manner. The parties entered into a Settlement Agreement in October, 1999 under which the Defendants were required to provide all specialized services to all Massachusetts residents with mental retardation or developmental disabilities who currently reside in nursing homes in the Commonwealth who have been determined to need such services."

It was further noted "that in May 2002, the Court ordered the Defendants to provide 'active treatment' to class members. Consistent with its coordinating authority, the Executive Office of Health and Human Services ("EOHHS") issued through its agencies (the Department of Mental Retardation, the Department of Public Health, the Division of Medical Assistance, and the Massachusetts Rehabilitation Commission) the policy titled "Active Treatment Standard for Specialized Services for Rolland Class Members". The policy directed DMR to work with nursing facility staff to incorporate specialized service plan strategies into each class member's nursing facility care plan through the development of an integrated DMR service plan called the Rolland Integrated Service Plan ("RISP"). The policy requires that DPH, under its regulatory authority, verify that nursing facilities have incorporated the specialized service plan strategies into the nursing facility care plan ("POC")."

Atty. Vendetti stated in part, "The amendments to the DPH regulations were developed with substantial input from the other Rolland agencies. After the informational briefing before the

Council on August 23, 2005, a public hearing was held on October 6, 2005. There was no testimony and no comments were received by the end of the comment period. Internally, the Division decided to clarify that "The Rolland Amendments" applied only to certified nursing facilities and revised the proposed amendments to include a definition of certified facility, and to include the word certified as a modifier before the word facility wherever it appeared in the amended portions of the regulations. The Division recommends the final promulgation of these amendments, as revised in Attachment A of your handout."

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the Request for **Final Promulgation of Amendments to 105 CMR 150.000 Licensing of Long Term Care Facilities ("The Rolland Amendments");** that a copy be forwarded to the Secretary of the Commonwealth for promulgation; and that a copy be attached and made a part of this record as **Exhibit No. 14, 834**.

**REQUEST FOR APPROVAL OF EMERGENCY AMENDMENTS TO 248 CMR 1.00-10.00: THE STATE PLUMBING CODE AND FUEL GAS CODE REGULATIONS:**

Mr. Howard Wensley, Representative from the State Department of Public Health to the State Board of Examiners of Plumbers and Gas Fitters, presented the amendments to 248 CMR 1.00-10.00 to the Council. He said, "The State Board of Plumbers and Gas Fitters is established by statute. It consists primarily of members appointed by the Governor, who are in the industry itself, including the Commissioners from the Department of Public Health and Public Safety, or their designee. This agency is responsible for promulgating all types of regulations relative to plumbers and gas fitters… There was an unfortunate death last winter caused by the blockage of an exhaust vent from what is called a direct vent or horizontally vented heating system. This gas appliance became blocked and was therefore not able to expel the carbon monoxide from the building, resulting in the death of a young child down in Plymouth. As a result of that, a couple of things have happened. First of all, the State Board of Plumbers looked at the situation and has proposed, and actually filed with the Secretary of State, emergency regulations which would require, among other things, carbon monoxide detectors to be installed when this equipment is installed in a home. It also will require that, on the outside of the building, there be a small posting so that it will be noted that these exhausts are present and, in case of heavy snow load emergency responders can deal with that particular situation. Also, at the same time, legislation was filed and a law was ultimately passed called Nicole's Law, which will require these carbon monoxide detectors to be installed pretty much in all buildings. There is a little bit of overlap at this particular point. Nicole's Law has been passed, but the regulations will not be effective or promulgated probably for about another hundred and eighty days."

Mr. Wensley continued, "In the Interim, what will be in place, is this regulation, which will require all gas combustion equipment in residential settings to also be accompanied by appropriate signage and carbon monoxide detectors, and we are requesting that the Department of Public Health accept this for public buildings. We have already held public hearings on it and in all likelihood I will probably be back at the next Council meeting, or the one after, for final promulgation of these regulations."

Staff's memorandum to Council, states: "These regulations seek to prevent carbon monoxide poisoning in residential buildings. Given that we are approaching the heating season in New England, it is important that they go into effect on an emergency basis. The intent of the regulations is to prevent the possibility of carbon monoxide poisoning in residential buildings that will have an installation of gas combustion equipment using a side wall exhaust system that terminates on the exterior of the building less than seven (7) feet above the outside grade. Because of the possibility of such an exhaust being blocked by snow or other obstruction, the regulations require the installation of at least one carbon monoxide detector in this circumstance. These regulations have been developed in conjunction with the State Fire Marshall following the death of a child last winter as a result of the blockage of the exhaust by snow accumulation. The primary provisions of the amendment are as follows:

- Requiring the presence of a carbon monoxide detector within the living area as well as on the same level as the combustion equipment. If the combustion equipment is installed in an attic or crawl space, the required detector must be installed on the next adjacent habitable floor level.

- Requiring an identification plate to be permanently mounted on the exterior of the building at a minimum height of eight (8) feet above grade directly in line with the exhaust vent terminal. This plate shall state "GAS VENT DIRECTLY BELOW, KEEP CLEAR OF ALL OBSTRUCTIONS".

- Requiring the manufacturer of a side wall horizontally-vented gas fueled equipment to provide detailed instructions for the installation of the venting system or venting system components.

- Exempting side wall horizontally-vented gas fueled equipment when it is installed separate from the building.

The Department of Public Health made the following comment: "These new requirements apply when side wall horizontally- vented gas fueled equipment has an exhaust vent that is less than seven feet above grade. The regulations should apply to such exhaust vents that are less than seven feet above grade or **other horizontal surface** and not just ground level to address circumstances where snow or other obstructions on decks or porches can block the exhaust vent. The Department has submitted comments to the Board on this problem, which will reportedly be addressed in the final regulations.

In closing, Staff noted, "The Board filed emergency regulations with the Secretary of State, effective October 6, 2005, for privately-owned residential buildings. At this time we are seeking the Council's approval of the application of these emergency regulations to state-owned residential buildings. A public hearing seeking comment on these amendments was held on November 2, 2005. Comments received at the public hearing and during the public comment period, which ended November 4, 2005, will be considered and the emergency regulations will be amended as appropriate. The Board expects to request the Council's approval of the final regulations in December."

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the Request for **Approval of Emergency Amendments to 248 CMR 1.00-10.00: The State Plumbing Code and Fuel Gas Code Regulations;** that a copy be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit No. 14, 835**.

**REQUEST TO PROMULGATE EMERGENCY AMENDMENTS TO 105 CMR 100.000: DETERMINATION OF NEED REGULATIONS:**

Attorney Carol Balulescu, Deputy General Counsel, Department of Public Health, noted, "The Department is proposing Emergency Amendments to 105 CMR 100.000, The Determination of Need Regulation. The purpose of the proposed change is to require full disclosure by all parties that seek to participate in a Determination of Need, or DoN, application process. The DoN process affords opportunities to Parties of Record, and other interested persons, to comment on DoN Applications and, in certain instances, to participate in proceedings before you. In addition to Ten Taxpayer Groups (TTGs), whose rights are specified in the DoN regulation, interested persons have an opportunity to offer oral and written testimony at public hearings, and may also submit written comments to the Department."

Attorney Balulescu said further, "In recent applications that were presented to you, comments were provided by TTGs and other interested parties, who acted as agents for undisclosed principles. Failure to disclose the party in interest hampered a fair and open discussion of comments by the Department and by you, and made it difficult for you to appropriately assess potential conflicts of interests. As you are aware, the DoN regulation currently prohibits the applicant, other parties, or their agents or representatives from initiating any oral or written communication with PHC members, regarding a pending application. When parties are not identified on the record, you have no way to recognize whether any contact may violate this prohibition."

In closing, Atty. Balulescu said, "The Department is requesting emergency promulgation so that these new requirements will take effect immediately. We plan to hold a public comment hearing on December 14, 2005, to receive comments, and will return to you, to provide a review of the testimony, to present any changes proposed in response to the testimony, and to request approval for final promulgation of the emergency amendments."

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the Request to **Promulgate Emergency Amendments to 105 CMR 100.000: Determination of Need Regulations**; that a copy be attached and made a part of this record as **Exhibit No. 14, 836**; and that the approved emergency amendment be forwarded to the Secretary of the Commonwealth for promulgation.

The meeting adjourned at 11:45 a.m.

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Commissioner

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Paul J. Cote, Jr.
Chair

LMH/lmh